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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,236	02/09/2004	Craig A. Rosen	PS751P1	7334

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,236	ROSEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-9 and 15-21* is/are pending in the application.

4a) Of the above claim(s) *1,2,9 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Appendix A and B*

DETAILED ACTION

Status of the Application

[1] Claims 1-2, 7-9, and 15-21 are pending in the application.

[2] Applicant's amendment to the claims, filed 14 September 2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's amendment to the specification, filed 14 September 2006, is acknowledged.

[4] Receipt of an information disclosure statement, filed 14 September 2006, is acknowledged.

Election/Restriction

[5] Applicant's election of Group VI, original claims 7-8, in the reply filed 14 September 2006, is acknowledged. It is noted that claims 15-20 read on the elected invention of Group VI and will be examined herein. Applicant's further election of SEQ ID NO:282 in the reply filed 14 September 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's request for rejoinder of process claims 1-2, 9, and 21 with product claims 7-8 and 15-20 is acknowledged (instant response at p. 8, top). However, as the product claims are not yet allowable, consideration of rejoinder of the process claims is not as yet required.

[6] Claims 1-2, 9, and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[7] Claims 7-8 and 15-20 are being examined on the merits.

Claim for Domestic Priority

[8] In the response filed 14 September 2006 at p. 8, top, applicant notes that the invention as disclosed in the instant application is supported by PCT/US03/04819, filed 20 February 2003, which claims benefit of US provisional application 60/358,554, filed 22 February 2002. Applicant's claim to domestic priority under 35 U.S.C. 120 and 119(e) to those applications as set forththese applications is acknowledged.

Information Disclosure Statement

[9] All references cited in the IDS filed 14 September 2006 have been considered by the examiner. A copy of Form PTO/SB/08 is attached to the instant Office action.

Oath/Declaration

[10] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: the country of residence for inventor Paul A. Moore is listed as MD. The

application data sheet filed 9 February 2004 also lists the country of residence for inventor Paul A. Moore is listed as MD.

[11] Although non-initialed and/or non-dated alterations have been made to the oath or declaration for inventor Ping Wei, this defect is corrected by the application data sheet filed 9 February 2004.

Specification/Informalities

[12] The attempt to incorporate subject matter into this application by reference to a hyperlink embedded in the specification (for example, page 82, top; p. 277, top; p. 316, middle) is improper. Incorporation of subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01 regarding hyperlinks in the specification and 608.01(p), paragraph I regarding incorporation by reference.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[13] Claim(s) 7-8 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 (claims 8, 17, and 19 dependent therefrom) and 15 (claims 16, 18, and 20 dependent therefrom) are indefinite in the recitation of "mature polypeptide encoded

by the HCPCB26 cDNA Clone ID in ATCC Deposit No:PTA-3845" as it is unclear from the specification and the claims as to the portion(s) of a polypeptide encoded by the HCPCB26 cDNA Clone ID in ATCC Deposit No:PTA-3845 that is/are considered to be "mature." It is suggested that applicant clarify the meaning of the term "mature" with respect to a polypeptide encoded by the HCPCB26 cDNA Clone ID in ATCC Deposit No:PTA-3845.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

[14] Claims 7, 15, and 17-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to polypeptides. The claims read on a product of nature, *i.e.,* a naturally-occurring polypeptide, and should be amended to indicate the hand of the inventor, e.g., by insertion of "purified" or "isolated". See MPEP § 2105.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[15] Claims 7-8 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" (MPEP 8th Ed., October 2006 Revision at pp. 2100-176 and 2100-183) and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

As support for the amendment to claims 7 and 15, applicant points to pp. 77, 141-142, and 203 of the specification. However, the examiner can find no support for the limitations of parts (b) to (g) of claims 7 and 15. As support for newly added claims 19-20, applicant points to pp. 526-528 of the specification. However, while this disclosure may support a polypeptide produced by expression in a mammalian host cell, it does not support a polypeptide produced by any host cell.

Applicant is invited to show support for the limitations at issue.

[16] Claims 7-8 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of he claimed invention. This is a written description rejection.

Claims 7 (claims 8, 17, and 19 dependent therefrom) and 15 (claims 16, 18, and 20 dependent therefrom) are drawn to SEQ ID NO:282 and a genus of variants of SEQ ID NO:282 as encompassed by the claims having any biological activity.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the specification discloses only a single representative species that falls within the recited genus of polypeptides, *i.e.*, SEQ ID NO:282. The specification fails to describe any additional representative species of the claimed genus of polypeptides. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be

achieved by disclosing only one species within the genus." In the instant case, the recited genus of proteins encompasses species that are widely variant in both structure and function, including (but not limited to) protein variants having function other than the activity of SEQ ID NO:282, *e.g.*, non-functional polypeptides. As such, the disclosure of the single representative species of SEQ ID NO:282 is insufficient to be representative of the attributes and features of all species encompassed by the claimed genus of proteins.

Given the lack of description of a representative number of polynucleotides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[17] Claims 7-8 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:282, does not reasonably provide enablement for all variants of SEQ ID NO:282 as broadly encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation is required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows:

(A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). MPEP 2164.04 states, "[w]hile the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection" and that "[t]he language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims." Accordingly, the Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: Claim 7 (claims 8, 17, and 19 dependent therefrom) is so broad as to encompass all polypeptides comprising an amino acid sequence that is at least 95% identical to a 30 amino acid fragment of SEQ ID NO:282, wherein the polypeptide can have any biological activity or function. Claim 15 (claims 16, 18, and 20 dependent therefrom) is so broad as to encompass all polypeptides comprising a 30 amino acid fragment of SEQ ID NO:282, wherein the polypeptide can have any biological activity or function. The enablement provided by the specification is not commensurate in scope with the claims with regard to the broad scope of proteins as

encompassed by the claims. In this case, the specification is enabling only for SEQ ID NO:282.

The state of the prior art; The level of one of ordinary skill; and The level of predictability in the art: The amino acid sequence of a polypeptide determines said polypeptide's structural and functional properties. Predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity/utility requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (*i.e.*, expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The positions within a protein's sequence where modifications can be made with a reasonable expectation of success in obtaining a polypeptide having the desired activity/utility are limited in any protein and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, *e.g.,* multiple substitutions. At the time of the invention, methods for isolating or generating variants of a given polypeptide were known in the art. However, neither the specification nor the state of the art at the time of the invention provided the necessary guidance for altering the polypeptide of SEQ ID NO:282 with an expectation of obtaining a polypeptide having the desired activity/utility. At the time of the invention, there was a high level of unpredictability associated with altering a polypeptide sequence with an expectation that the polypeptide will maintain the desired activity/utility. For example, Branden et al. ("Introduction to Protein Structure", Garland

Publishing Inc., New York) teach "[p]rotein engineers frequently have been surprised by the range of effects caused by single mutations that they hoped would change only one specific and simple property in enzymes" and "[t]he often surprising results of such experiments reveal how little we know about the rules of protein stability... ...they also serve to emphasize how difficult it is to design *de novo* stable proteins with specific functions" (page 247). The teachings of Branden et al. are currently exemplified by the reference of Witkowski et al. (*Biochemistry* 38:11643-11650), which teaches that only a single amino acid substitution results in conversion of the parent polypeptide's activity from a beta-ketoacyl synthase to a malonyl decarboxylase (see *e.g.*, Table 1, page 11647).

The amount of direction provided by the inventor and The existence of working examples: The specification discloses only a single working example of the claimed polypeptide, *i.e.,* SEQ ID NO:282. The specification fails to disclose any specific guidance for altering the amino acid sequence of SEQ ID NO:282 with an expectation that the resulting variants thereof as encompassed by the claims will maintain the desired activity/utility. Further, the specification fails to provide guidance for using those polypeptides that do not maintain the activity of SEQ ID NO:282.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of isolating or generating variants of a polypeptide were known in the art at the time of the invention, it was not routine in the art to screen – by a purely trial and error process – for all polypeptide variants having a

substantial number of modifications as encompassed by the claims for those polypeptides having the desired activity/utility.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of required experimentation, it is the examiner's position that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

[18] Claims 7-8 and 15-20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn (in relevant part) to a polypeptide encoded by a vector in a novel strain, *i.e.,* ATCC Deposit No:PTA-3845. Since the strain is essential to the

claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The method of making the recited vector is not fully disclosed, nor have all the sequences required for its construction been shown to be publicly known and freely available. The enablement requirement of 35 U.S.C. § 112 may be satisfied by a deposit of the strain. The specification does not disclose a repeatable process to obtain the strain and it is not apparent if the vector sequences are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition – with the possible exception of 37 CFR 1.808 – released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;

2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

4. the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[19] Claims 7, 15, and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Number Q93091 (GI:3123285, July 1998).

The claims are drawn to the polypeptide of SEQ ID NO:282 and variants thereof as encompassed by the claims. It is noted that claims 19-20 are product-by-process claims and according to MPEP 2113, "'[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.'"

GenBank Accession Number Q93091 teaches a polypeptide, human Ribonuclease K6, that has a sequence that is 100% identical to SEQ ID NO:282 herein (see Appendix A sequence alignment). This anticipates claims 7, 15, and 19-20 as written.

For clarification, it is noted that the alignment indicates a less than 100% identity between SEQ ID NO:282 and GenBank Accession Number Q93091 because of a single mismatch at position 89. However, it is noted that the mismatch is due to the presence of an "X" amino acid in the sequence of SEQ ID NO:282, which is indicated as being "any of the naturally occurring L-amino acids" at p. 177 of the sequence listing filed on 9 February 2004.

[20] Claims 7-8 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al. (US Patent 5,866,119).

The claims are drawn to the polypeptide of SEQ ID NO:282 and variants thereof as encompassed by the claims. It is noted that claims 19-20 are product-by-process claims and according to MPEP 2113, "'[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.'"

Bandman et al. teaches a polypeptide, SEQ ID NO:3, having a sequence that, with the exception of a single mismatch at position 76, is identical to SEQ ID NO:282 herein (see Appendix B sequence alignment). This anticipates claims 7, 15, and 19-20 as written. Bandman et al. teaches the polypeptide can be in glycosylated form or fused to a heterologous sequence (column 6, lines 17-18 and column 16, lines 55-65). This anticipates claims 8 and 16-18 as written.

For clarification, it is noted that the alignment of Appendix B also indicates a mismatch at position 89. However, it is noted that the mismatch is due to the presence of an "X" amino acid in the sequence of SEQ ID NO:282, which is indicated as being "any of the naturally occurring L-amino acids" at p. 177 of the sequence listing filed on 9 February 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[21] Claim(s) 8 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Number Q93091 in view of Bandman et al.

Claims 8 and 16-18 limit the polypeptide of claims 7 or 15 to comprising a heterologous amino acid sequence or to being glycosylated.

GenBank Accession Number Q93091 discloses human Ribonuclease K6 that is 100% identical to SEQ ID NO:282 herein as noted above.

Bandman et al. further teaches human Ribonuclease K6 is suggested to have a role in host defense (column 1, lines 50-53), SEQ ID NO:3 is closely related to the structure of Ribonuclease K6 (column 9, lines 23-25), and SEQ ID NO:3 is useful for identifying potential therapeutic compounds (*e.g.,* column 1, lines 26-59 and column 17, lines 29-33). Bandman et al. teaches that an expression host cell can be chosen for its ability to provide post-translational modifications to an expressed protein, *e.g.,* glycosylation (column 14, lines 51-55) and provides examples of such hosts (column 14, lines 61-62) and teaches methods of recombinantly producing proteins using such hosts (columns 14-16).

Therefore at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of GenBank Accession Number Q93091 and Bandman et al. to use a mammalian expression host as disclosed by Bandman et al. that provides post-translational modification, particularly glycosylation, and isolate the expressed protein. Because the polypeptide of GenBank Accession Number Q93091 is a human protein, one would have been motivated to recombinantly express the Ribonuclease K6 of GenBank Accession Number Q93091 using a mammalian host as taught by the method of Bandman et al. One would have been motivated to recover the produced protein in order to analyze its role in host defense

and to identify potential modulators as suggested by Bandman et al. One would have a reasonable expectation of success for recombinantly expressing the Ribonuclease K6 of GenBank Accession Number Q93091 using a mammalian host as taught by Bandman et al. and recovering the produced protein because of the results of GenBank Accession Number Q93091 and Bandman et al. Therefore, claims 8 and 16-18, drawn to a polypeptide as described above, would have been obvious to one of ordinary skill in the art at the time of the invention.

While it is acknowledged that the combination of references does not specifically teach a glycosylated form of the polypeptide of GenBank Accession Number Q93091, a glycosylated form of GenBank Accession Number Q93091 would be an inherent result of expressing the polypeptide in a mammalian host cell as taught by Bandman et al.

Claim Rejections – Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[22] Claims 7, 15, and 19-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 and 16 reciting SEQ ID NO:40 of co-pending Application No. 10/921,235. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 7, 15, and 19-20 of the instant application are generic to all that is recited in claims 11-12 and 16 reciting SEQ ID NO:40 of the co-pending application, i.e., claims 7, 15, and 19-20 of the instant application are anticipated by claims 11-12 and 16 reciting SEQ ID NO:40 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

[23] Status of the claims:

Claims 1-2, 7-9, and 15-21 are pending.

Claims 1-2, 9, and 21 are withdrawn from consideration.

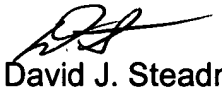
Claims 7-8 and 15-20 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656

APPENDIX A

Query sequence 1

>GI|3123285|SP|Q93091|RNK6_HUMAN RIBONUCLEASE K6 PRECURSOR (RNASE K6)
MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC
KHQNTFLHDSFQNVAAVCDLLSIVCKNRRHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA
QYKFFIVACDPPQKSDPPYKLVPVHLDSIL

Query sequence 2

>SEQ ID NO:282
MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC
KHQNTFLHDSFQNVAAVCDLLSIVCKNRXHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA
QYKFFIVACDPPQKSDPPYKLVPVHLDSIL

Full-length alignment between two sequences

>>SEQ ID NO:282 (150 aa)
s-w opt: 1086 Z-score: 1344.2 bits: 254.8 E(): 4.6e-73
Smith-Waterman score: 1086; 99.333% identity (99.333% ungapped) in 150 aa overlap (1-150:1-150)

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               10        20        30        40        50        60
GI|312 MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC
       ::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::::
SEQ    MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC
               10        20        30        40        50        60

               70        80        90       100       110       120
GI|312 KHQNTFLHDSFQNVAAVCDLLSIVCKNRRHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA
       ::::::::::::::::::::::::::: :::::::::::::::::::::::::::::::
SEQ    KHQNTFLHDSFQNVAAVCDLLSIVCKNRXHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA
               70        80        90       100       110       120

              130       140       150
GI|312 QYKFFIVACDPPQKSDPPYKLVPVHLDSIL
       ::::::::::::::::::::::::::::::
SEQ    QYKFFIVACDPPQKSDPPYKLVPVHLDSIL
              130       140       150
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APPENDIX B

```
US-08-867-676-3
; Sequence 3, Application US/08867676
; Patent No. 5866119
;  GENERAL INFORMATION:
;    APPLICANT:  Bandman, Olga
;    APPLICANT:  Lal, Preeti
;    APPLICANT:  Corley, Neil C.
;    TITLE OF INVENTION:  NEW HUMAN RIBONUCLEASE
;    NUMBER OF SEQUENCES:  3
;    CORRESPONDENCE ADDRESS:
;      ADDRESSEE:  Incyte Pharmaceuticals, Inc.
;      STREET:  3174 Porter Drive
;      CITY:  Palo Alto
;      STATE:  CA
;      COUNTRY:  USA
;      ZIP:  94304
;    COMPUTER READABLE FORM:
;      MEDIUM TYPE:  Diskette
;      COMPUTER:  IBM Compatible
;      OPERATING SYSTEM:  DOS
;      SOFTWARE:  FastSEQ for Windows Version 2.0
;    CURRENT APPLICATION DATA:
;      APPLICATION NUMBER:  US/08/867,676
;      FILING DATE:
;      CLASSIFICATION:  435
;    PRIOR APPLICATION DATA:
;      APPLICATION NUMBER:
;      FILING DATE:
;    ATTORNEY/AGENT INFORMATION:
;      NAME:  Billings, Lucy J J
;      REGISTRATION NUMBER:  36,749
;      REFERENCE/DOCKET NUMBER:  PF-0304 US
;    TELECOMMUNICATION INFORMATION:
;      TELEPHONE:  415-855-0555
;      TELEFAX:  415-845-4166
;      TELEX:
;  INFORMATION FOR SEQ ID NO:  3:
;    SEQUENCE CHARACTERISTICS:
;      LENGTH:  150 amino acids
;      TYPE:  amino acid
;      STRANDEDNESS:  single
;      TOPOLOGY:  linear
;    IMMEDIATE SOURCE:
;      LIBRARY:  GenBank
;      CLONE:  1513102
US-08-867-676-3

  Query Match             99.3%;  Score 830;  DB 1;  Length 150;
  Best Local Similarity   98.7%;  Pred. No. 3.6e-91;
  Matches  148;  Conservative    0;  Mismatches    2;  Indels    0;  Gaps    0;

Qy          1 MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MVLCFPLLLLLLVLWGPVCPLHAWPKRLTKAHWFEIQHIQPSPLQCNRAMSGINNYTQHC 60

Qy         61 KHQNTFLHDSFQNVAAVCDLLSIVCKNRXHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA 120
              ||||||||||||||| |||||||||||| ||||||||||||||||||||||||||||||
Db         61 KHQNTFLHDSFQNVARVCDLLSIVCKNRRHNCHQSSKPVNMTDCRLTSGKYPQCRYSAAA 120

Qy        121 QYKFFIVACDPPQKSDPPYKLVPVHLDSIL 150
              ||||||||||||||||||||||||||||||
Db        121 QYKFFIVACDPPQKSDPPYKLVPVHLDSIL 150
```